**PATENT** 

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Thomas D. Doerr et al.

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Art Unit:

2166

Docket No.:

951130.90011

## SUBMISSION OF FORMAL DRAWINGS

OFFICIAL DRAFTSMAN

Commissioner for Patents Washington, D. C. 20231

Sir:

Enclosed herewith are twenty-three (23) sheets of formal drawings, including Figs. 1-32 in the above specified case. Please enter these drawings into the file.

The Commissioner is hereby authorized to charge any cost that may be due to Deposit

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Respectfully submitted,

**THOMAS** DOERR et al.

Keith M. Baxter

Reg. No. 31,233

Attorney for Applicant

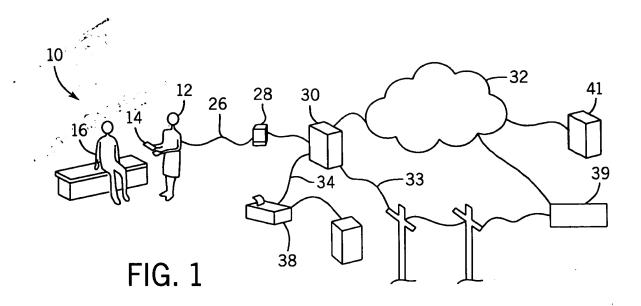
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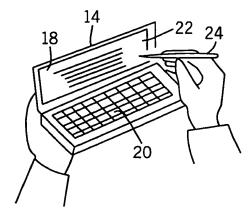
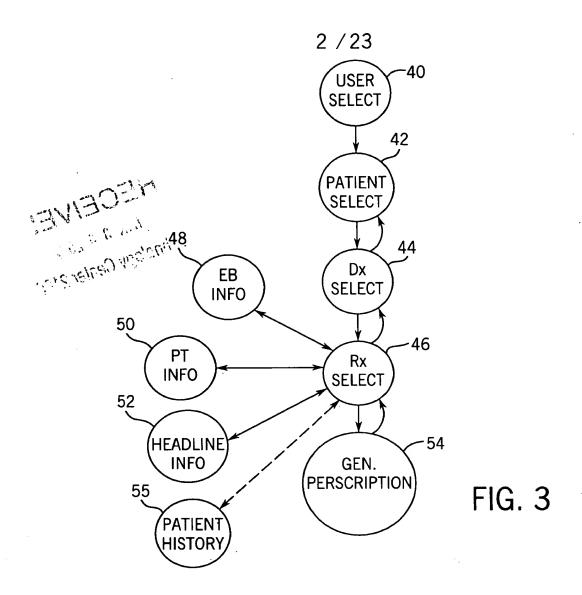
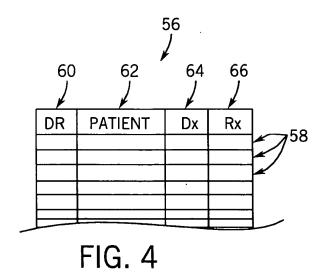
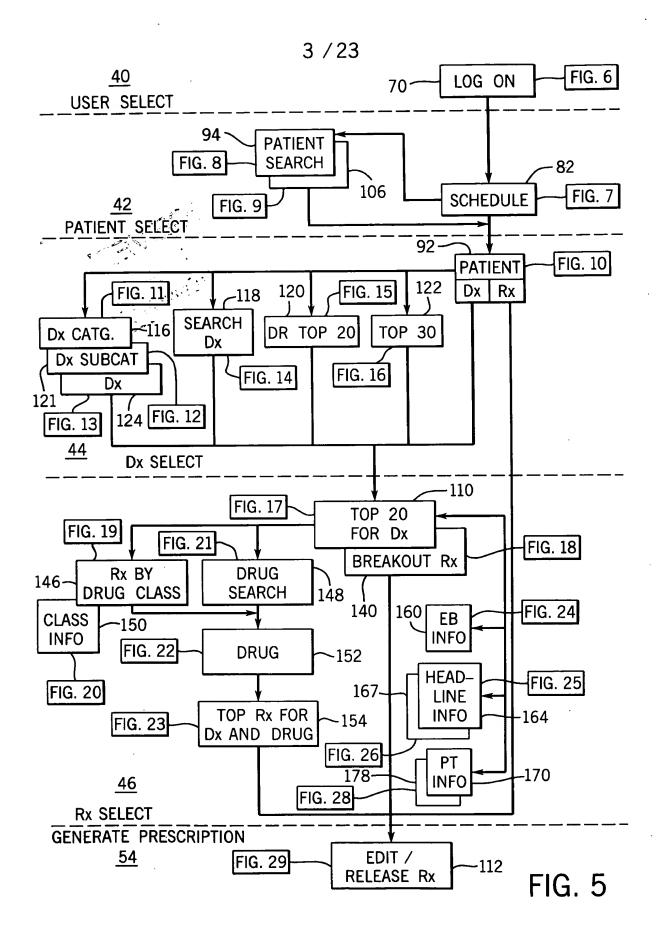


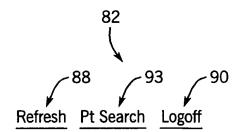
FIG. 2







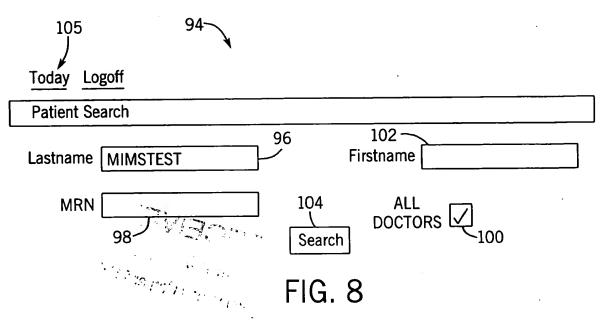
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Prescribing User Logon-Welby Medical
Select your facility and user id from the list below, then enter your WELLinx password.  74  72
FACILITY: Welby Medical Group   ✓ LOCATION: Southwest Clinic   ✓
USER ID: MARCUS WELBY
PASSWORD: Logon
78
FIG. 6



Select Pati	ent-10 Patients found for tod	ay		
09:00	WELLINX, DAVID		13:00	MILLER, ELLEN
09:30	ADAMS, LORRAINE		13:30	JOHNSON, SHARON
10:00	SMITH, PATRICIA		14:00	LEE, KEVIN
10:30	DAVIS, ROGER		15:00	ANDERSON, JAMES
11:00	OLSON, MICHAEL		15:30	JEFFERSON, SCOTT
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FIG. 7





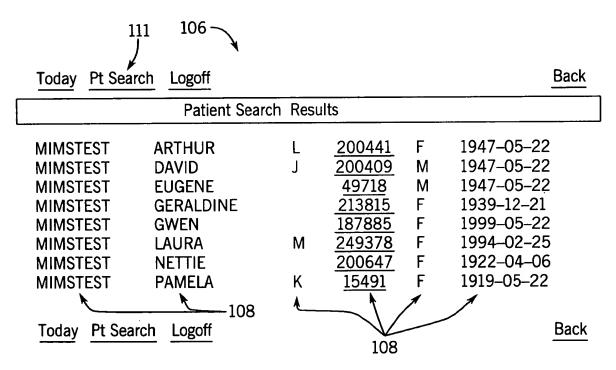


FIG. 9

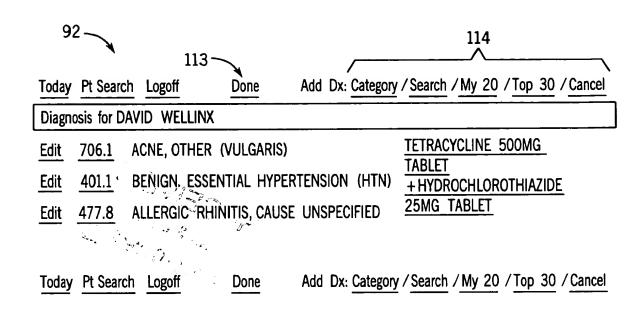


FIG. 10

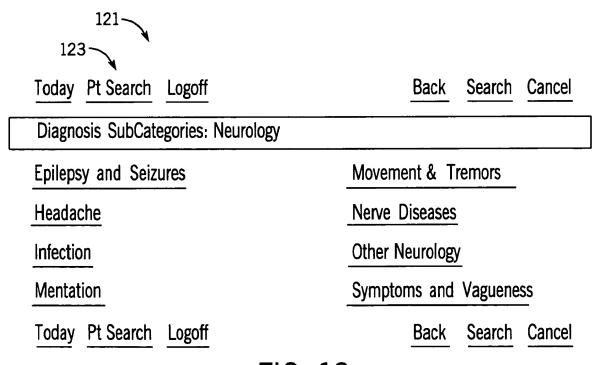
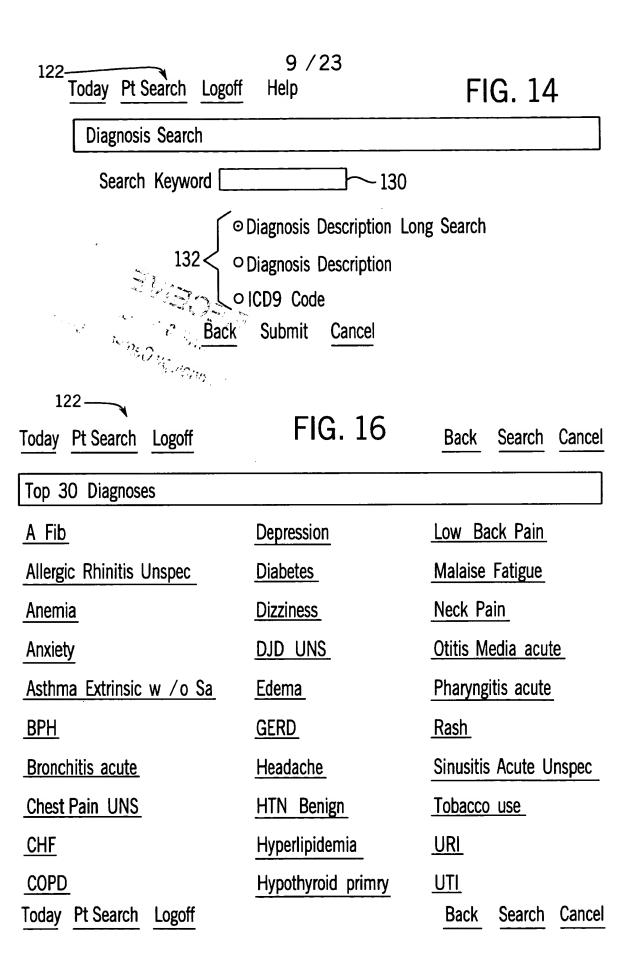


FIG. 12

116		
Today Pt Search Logoff		Back Search Cancel
Diagnosis Categories		
Abnormal Test Results	Infectious Diseases	Skeletal: Axial
Blood Vessels, Edema, Lymph	Kidney / Nephrology	Skeletal: Leg
Congenital	Lungs Allergy & Sleep	Skeletal: Musculoskeletal
Diabetes	Miscellaneous	Skin
E-Codes (secondary diagnosis only)	Mouth 119	Syndromes
Ear Nose Throat Mouth	Neurology -	Trauma
Endocrine / Metabolic	OB / GYN & Fetus / Newborn	Urology
Eyes	Other V Codes	V-Codes: Top 15 (IM)
Gastrointestinal	Pediatrics	VCodes: Personal Hx of Dz
Heart	Psychiatry	
Hematology Oncology	Skeletal: Arm	
Today Pt Search Logoff	FIG. 11	Back Search Cancel

Back Cancel					FIG. 13							( <u>)</u>			R HEADACHE)		Back Cancel
Today Pt Search Logoff	Diagnosis Description: Neurology: Headache	346.00 CLASSICAL MIGRAINE W/O MENTION OF INTRACTABLE MIGRAINÉ	346.01 CLASSICAL MIGRAINE WITH INTRACTABLE MIGRAINE, SO STATED	346.10 COMMON MIGRAINE W/O MENTION OF INTRACTABLE MIGRAINE	346.11 COMMON MIGRAINE WITH INTRACTABLE MIGRAINE, SO STATED	346.80 MIGRAINE NEC / NOT INTRCBL	346.91 MIGRAINE, UNSPECIFIED, W/INTRACTABLE MIGRAINE	346.90 MIGRAINE, UNSPECIFIED, W/O MENTION OF RETRACTABLE MIGRAINE	346.81 OTHER FORMS OF MIGRAINE WITH INTRACTABLE MIGRAINE, SO STATED	310.2 POSTCONCUSSION SYNDROME	625.4 PREMENSTRUAL TENSION SYNDROMES (PMS)(MENSTRUAL MIGRAINE)	349.0 REACTION TO SPINAL OR LUMBAR PUNCTURE (POST-SPINAL TAP HEADACHE)	307.81 TENSION HEADACHE	047.9 UNSPECIFIED VIRAL MENINGITIS	346.21 VARIANTS OF MIGRAINE WITH INTRACTABLE MIGRAINE, SO STATED (CLUSTER HEADACHE)	346.20 VARIENTS OF MIGRAINE-NOT INTRACTABLE (CLUSTER HEADACHE)	Today Pt Search Logoff
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		Dr. Poln	
Today Pt Search Logoff		Search Cancel	
Doctor Top 20 Diagnoses		J.	
HTN UNSPEC.	KNEE PAIN	CRAMPS IN LIMB	
FLU VACCINE	PNEUMOVAX / PREVNAR VACC.	POSTMENOPAUSE HORMONE RX	
LAB EXAM	INSOMNIA NOS	ROUTINE MEDICAL EXAM	10
LIPOID METABOL DISDORD NOS	DIARRHEA	SCREEN FOR PROSTATE CA	/ 2
LONG TERM USE OF HIRISK RX	CVA	SHOULDER PAIN	<b>J</b>
LONG TERM USE OF ANTICOAG	SKIN LESION BENIGN NOS	SCREEN FOR RECTAL CA	
OBESITY MORDIB	IRRITABLE BOWEL SYNDROME		
Today Pt Search Logoff			

FIG. 15

110	_				2	4/			<del>-</del> -	
Today Pt Search Logoff	earch Logoff			Select Rx by Class	c by Cla		ct for of	힐	<del>-</del>	
Top Rx for 401.1: BENIGN ESSENTIAL HYPERTENSION (HTN)	401.1: BENIGN ESSENTIA	HYPERTENSION (HTN)	_	00	PT Info	**	EB Info	747		
Drug / Dosage Name	Drug / Dosage Name	Price	S	SIG	Oty	Refills FPRN	PRN		FIC 17	-
Diuretics	Diuretics	Diuretics and beta blockers are first linestherapy	re firs	t line th	erapy		25		<u>.</u>	-1
Edit ENALAPRIL (Vasotec) 10MG TABLET	APRIL (Vasotec) 10MG TABLE	⊨.l	-	1 00	· *:	, w	z	Drug Info		
Edit + HCTZ (HydroDiuril) 25MG TABLET	TZ (HydroDiuril) 25MG TABLET		_	1 00	8	=	Z	Drug Info		
+ATENOLOL (Tenormin)	ENOLOL (Tenormin)							Drug Info		
+ CAPTOPRIL (Capoten)	PTOPRIL (Capoten)							Drug Info		
Edit TRIAMTERENE / HCTZ 25 / 37.5MG TABLET	MTERENE / HCTZ 25 /37.5MG	TABLET	_	1 00	8	က	Z	Drug Info		
Edit ENALAPRIL (Vasotec) 20MG TABLET	JAPRIL (Vasotec) 20MG TABLET		_	1 @	96	က	Z	Drug Info		
Edit METOPROLOL SUCCINATE (Toprol XL)	OPROLOL SUCCINATE (Toprol XL		•	1 00	30	=	Z	Drug Info		
Edit + METOPROLOL 50MG TABLET	TOPROLOL 50MG TABLET	10		1 BID	09	Ħ	z	Drug Info		
Edit +LOPRESSOR 50MG TABLET	_	10	1	OB	99	=	z	Orug Info		
-Edit DILACOR XR 120MG CAPSULE SA		i		1 QD	8	က	z	Drug Info		
Today Pt Search Logoff	earch Logoff			Select Rx by Class	k by Cla		ct for ot	Select for other Drug Cancel	<u> </u>	

Today	Pt Search Logoff	Sele	ect Rx by (	Class	Select for o	ther Drug	Cancel
Top Rx	for 401.1: BENIGN ESSENTIAL	HYPERTE	ENSION (F	HTN)	PT Info	EB Ir	<u>nfo</u>
	Drug / Dosage Name	Price	SIG	Qty	Refills	PRN	
	Diuretics and	beta blo	ckers are	first l	ine thera	ру	
<u>Edit</u>	+TENORMIN 50MG TABLET	10	1 QD	30	11	N	Drug Info
Edit	+ATENOLOL 50MG TABLET	10	1 QD	30	11	N	Drug Info
Edit	ATENOLOL 100MG TABLET		1 QD	90	3	N	Drug Info
<u>Edit</u>	ATENOLOL 100MG TABLET		1 QD	100	3	N	Drug Info
<u>Edit</u>	ATENOLOL 100MG TABLET		1 QD	30	11	N	Drug Info
Edit	TENORMIN 100MG TABLET		1 QD	90	3	N	Drug Info
Today	Pt Search Logoff	Sele	ect Rx by (	Class	Select for o	ther Drug	Cancel

FIG. 18

Today Pt Search Logoff	Cancel	Search	for other Drug	
DRUG CLASSES				
Diagnosis 346.00: CLASSICAL MIGRAINE W /O MENTION	OF INT	RACTA	BLE MIGR	EB Info
Acetaminophen	1		Class Info	
+ Analgesic ,adjuncts	3		Class Info	
+ Beta Blockers	5		Class Info	
Calcium Channel Blockers	1		Class Info	
GI-Prokinetic	1		Class Info	
Headache-ergots	3		Class Info	
Headache-other	8			
Headache-triptans	5		Class Info	
+NSAIDs	22	)	Class Info	
Narcotics-Mild	8		Class Info	
Salicylates	2		Class Info	
Today Pt Search Logoff	Cancel	Search	for other Drug	

FIG. 19

A
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15

FIG. 20

a

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ANALGESIC MEDICATIONS	HIGHLIGHTS	• ULTRAM 100mg = TYLENOL 1000mg, LESS EFFECTIVE THAN IBUPROFEN 400mg MORE INFO	• TRAMADOL IS LESS EFFECTIVE THAN VICODIN IN ACUTE PAIN MORE INFO • REASONS TO AVOID DEMEROL MORE INFO	CONTENTS	TREATMENT OPTIONS LOWER POTENCY NARCOTICS	ACETAMINOPHEN STRONGER NARCOTICS SALICYLATES ADJUNCTIVE MEDICATIONS	NSAID COX 2 INHIBITOR	TREATMENT OPTIONS (REFER TO INFORMATION PRESENTED IN FOLLOWING SECTIONS FOR EFFICACY AND DOSING INFORMATION)

CHRONIC, CONTINUOUS PAIN WARRANTS USE OF SCHEDULED ADMINISTRATION TIMES INSTEAD OF PM DOSING, AND USE OF EXTENDED RELEASE ANALGESIC PREPARATIONS

MILD PAIN – ACETAMINOPHEN, SALICYLATES, NSAIDS, ADJUVANT MEDICATIONS (SELECTED SITUATIONS SUCH AS NEUROPATHIC PAIN)

Severe pain - Strong opiate /opioids (i.e. morphine, hydromorphone, levorphanol) +/- all of the above MODERATE PAIN - ALL OF THE ABOVE AS WELL AS WEAK OPIATE / OPIOID DRUGS (i.e. CODEINE, OXYCODONE)

IMMEDIATE RELEASE (IR) DOSAGE FORMS ARE APPROPRIATE FOR TREATMENT OF ACUTE OR EPISODIC PAIN, OR TO IMPROVE ANALGESIA DURING BREAKTHROUGH PAIN.

NSAIDS IN COMBINATION WITH OPIOIDS MAY BE HELPFUL FOR PAIN RESULTING FROM BONE METASTASES

CORTICOSTEROIDS (i.e. DEXAMETHASONE) MAY BE HELPFUL FOR SITUATIONS INVOLVING NERVE COMPRESSION OR INCREASED INTRACRANIAL PRESSURE.

ANTIDEPRESSANTS AND ANTICONVULSANTS HAVE BEEN USED IN NEUROPATHIC PAIN.

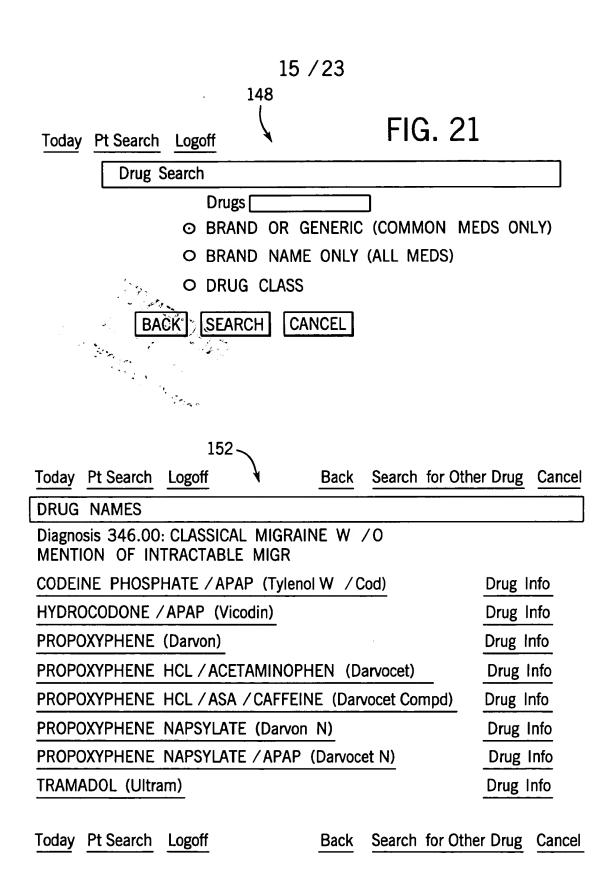


FIG. 22

1	154						
Today	Pt Search Logoff		<u>B</u>	ack S	elect for o	ther Drug	Cancel
Drug	Dosage						
Diagno	sis 346.00: CLASSICAL MIGRAINE W /O I	MENTION OF	NTRACTABLE N	MIGR			
	Drug	Price	SIG	Qty	Refills	PRN	Info
Edit	TYLENOL W/CODEINE ELIXIR		5 Q 6HR	120	0	N	Drug Info
<u>Edit</u>	TYLENOL W/CODEINE #2 TABLET		2 Q 4HR	60	0	N	Drug Info
<u>Edit</u>	TYLENOL W/CODEINE #3 TABLET		1 Q 4HR	30	1	Υ	Drug Info
<u>Edit</u>	TYLENOL W CODEINE #4 TABLET		1 Q 4HR	30	0	Υ	Drug Info
<u>Edit</u>	ACETAMINOPHEN / COD #3 TABLET		1 Q 4HR	30	1	Υ	Drug Info
<u>Edit</u>	ACETAMINOPHEN W / COD ELIXIR		5 Q 6HR	120	0	N	Drug Info
<u>Edit</u>	TY-PAP W /CODEINE ELIXIR		5 Q 6HR	120	0	N	Drug Info
Edit	MI-CODE ELIXIR		5 Q 6HR	120	0	N	Drug Info
<u>Edit</u>	ACETAMINOPHEN / CODEINE SOLN						
<u>Edit</u>	ACETAMINOPHEN /COD ELIXIR		5 Q 6HR	120	0	N	Drug Info
Today	Pt Search Logoff		В	ack S	elect for o	ther Drug	Cancel

FIG. 23

# PRIMARY HEADACHE DISORDERS

## HIGHLIGHTS

- TAILOR MIGRAINE & TO SEVERITY OF HEADACHE OR PRIOR RESPONSE. MORE INFO
- USE ABORTIVE THERAPIES NO MORE OFTEN THAN TWICE WEEKLY TO PREVENT CHRONIC DAILY HEADACHES. MORE INFO
- NSAIDS AND EXCEDRIN MIGRAINE ARE FIRST LINE FOR PATIENTS WITH MILD-MODERATE MIGRAINE. MORE INFO
- Use Migrane-specific agents (Triptans, DHE, Ergotamine) in Patients with More severe Headaches or if Unresponsive to NSAIDs and OTC analgesics. <u>More Info</u>
- DICLOFENAC K<sup>+</sup>. EQUAL EFFICACY, BUT LESS NAUSEA THAN SUMATRIPTAN 100mg. MORE INFO
- NSAID / METOCLOPRAMIDE AS EFFECTIVE AS ORAL SUMATRIPTAN FOR MODERATE-SEVERE MIGRAINE. MORE INFO

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NON-DRUG THERAPY

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ABORTIVE THARAPY GUIDELINES

COMPARATIVE STUDIES OF ABORTIVE DRUGS

MIGRAINE PROPHYLAXIS

MIGRAINE PATIENT TALKING POINTS

TREATMENT OF TENSION-TYPE HEADACHE

TREATMENT OF CLUSTER HEADACHE

**GUIDELINES ON THE WEB** 

**TRIPTANS** 

<u>DIHYDROERGOTAMINE (DHE)</u>

PATIENT INFORMATION

# CLINICAL FEATURES (ADAPTED FROM MAYO CLIN PROC 1996;71:1055)

FEATURE	MIGRAINE	TENSION-TYPE HEADACHE	CLUSTER HEADACHE
PREVALENCE	COMMON	COMMON	RARE
AURA	PRESENT IN 15%	NONE	NONE
SITE OF PAIN	HEMICRANIAL, BILATERAL	BILATERAL, OCCIPITAL, FRONTAL	UNILATERAL, FRONTOTEMPORAL

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- DICLOFENAC POTASSIUM: EQUAL EFFICACY BUT LESS NAUSEA THAN SUMATRIPTAN 100mg. (ANON. CEPHALAGIA 1999;19(4):232-40) DICLOFENAC POTASSIUM 50mg COSTS LESS THAN SUMATRIPTAN 100mg (LESS THAN \$2 VS \$34).
- ASA 900mg PLUS METOCLOPRAMIDE 10mg (<\$2) AS EFFECTIVE AS SUMATRIPTAN 100mg (\$32) IN THE TREATMENT OF MODERATE-SEVERE MIGRAINE. (TFELT-HANSEN P LANCET 1995;346:923-26) (ANON. EUR NEUROL 1992;32:177-84)
- SC SUMATRIPTAN ASSOCIATED. WITH MORE HEADACHE RECURRENCE THAN DHE NASAL SPRAY. SUMATRIPTAN
  6mg SC PROVIDED BETTER RELIEF OF HEADACHE AND ASSOCIATED SYMPTOMS THAN DHE NASAL SPRAY 1mg,
  HOWEVER HEADACHE RECURRED MORE COMMONLY AFTER TREATMENT WITH SUMATRIPTAN (31% VS 17%). BECAUSE
  THE DOSE OF DHE USED IN THIS STUDY IS BELOW THE RECOMMENDED DOSE OF 2mg, IT IS DIFFICULT TO COMPARE THE
  EFFICACY FOR HEADACHE RELIEF. (TOUCHON J. NEUROLOGY 1996;47:361-5) PATIENTS WITH LONG DURATION HEADACHES
  MAY BENEFIT FROM INTRANASAL DHE.
- ORAL SUMATRIPTAN MORE EFFECTIVE THAN ERGOTAMINE / CAFFEINE, BUT HAS HIGHER RECURRENCE RATE. IN A RCT INVOLVING 466 PATIENTS, IMPROVEMENT IN PAIN AT 2 HOURS OCURRED IN 66% OF PATIENTS TREATED WITH ORAL SUMATRIPTAN VS 48% OF PATIENTS TREATED WITH A COMBINATION OF ERGOTAMINE AND CAFFEINE (CAFERGOT©). HOWEVER, HEADACHES RECURRED IN 41% IN THE SUMATRIPTAN GROUP, COMPARED TO 30% OF THE ERGOTAMINE / CAFFEINE GROUP. SIDE EFFECTS WERE COMPARABLE. (ANNON. EUR NEUROLOGY 1991;31:314-22)

# MIGRAINE PROPHYLAXIS

- GENERAL INFORMATION
- GUIDELINES
- DRUG TABLE

FIG. 25

# FIG. 26

ACUTE TREATMENT OF MIGRAINE ATTACKS: EFFICACY AND SAFETY OF A NONSTEROIDAL ANTI-INFLAMMATORY DRUG, DICLOFENAC-POTASSIUM, IN COMPARISON TO ORAL SUMATRIPTAN AND PLACEBO ANON. CEPHALALGIA 1999; 19(4): 232-40

INTERVENTION: DICLOFENAC-K 50mg VS DICLOFENAC-K 100mg VS SUMATRIPTAN 100mg VS PLACEBO (ALL PATIENTS RECEIVED ALL FOUR TREATMENTS STUDY DESIGN: DOUBLE-BLIND, CROSS-OVER RCT IN 156 ADULTS WITH MIGRAINE +/- AURA (2-6 MIGRAINES / MONTH) OVER A PERIOD OF 3 MONTHS)

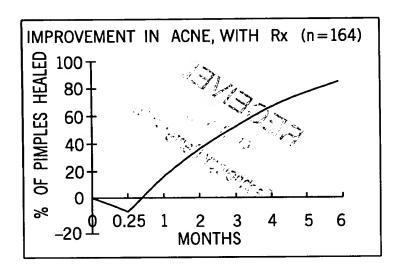
USE OF RESCUE MEDICATION IN THE PLACEBO GROUP COULD HAVE CONFOUNDED THESE RESULTS. AT?Ž∜HR AFTER DOSING, THERE WAS LESS NAUSEA IN OCCURRED IN THE SUMATRIPTAN GROUP COMPARED TO THE OTHER GROUPS (31% VS 12-18%), HOWEVER THERE WAS NO DIFFERENCE IN THE RATE OF RESULTS: HEADACHE PAIN 2 HR AFTER DOSING (BASED ON VAS): BOTH DOSES DICLOFENAC AND SUMATRIPIAN SUPERIOR TO PLACEBO, DICLOFENAC 8 HOUR OBSERVATION PERIOD. SIGNIFICANT PAIN RELIEF OCCURRED AT 60 MIN WITH DICLOFENACIVS, 90 MIN WITH SUMATRIPTAN. THERE WAS NO DIFFERENCE BETWEEN ACTIVE TREATMENT GROUPS IN THE USE OF RESCUE MEDICATION (36% VS 41%). THERE WAS NO DIFFERENCE BETWEEN GROUPS IN RATE OF HEADACHE RECURRENCE (22–24% FOR DICLOFENAC, 26% FOR SUMATRIPTAN, AND 19% FOR PLACEBO), HOWEVER THE INCREASED DOSING, THERE WAS LESS VOMITING IN THE DICLOFENAC AND PLACEBO GROUPS COMPARED TO THE SUMATRIPTAN GROUP (2 HR. 3–7% VS 13%). AT 50mg=100mg, BOTH DOSES DICLOFENAC=SUMATRIPTAN ACTIVE TREATMENTS EQUALLY EFFECTIVE TO EACH OTHER AND SUPERIOR TO PLACEBO OVER DICLOFENAC GROUPS COMPARED TO SUMATRIPTAN AND PLACEBO GROUPS (22–27% VS 41–43%). AT 8 HR AFTER DOSING, THERE WAS LESS NAUSEA 8HR AFTER DOSING, VOMITING WAS DECREASED IN THE DICLOFENAC GROUPS COMPARED TO SUMATRIPTAN (2-4% VS 10%). MORE ADVERSE EVENTS IN THE DICLOFENAC AND SUMATRIPTAN GROUPS COMPARED TO PLACEBO (DICLOFENAC 15-19%, SUMATRIPTAN 28%, PLACEBO 39%). AT 2HR AFTER DISCONTINUATION DUE TO ADVERSE EVENTS. DIZZINESS, PARESTHESIA, ASTHENIA, AND TACHYCARDIA APPEARED TO OCCUR MORE COMMONLY IN THE SUMATRIPTAN GROUP.

COMMENTS: SEVERITY OF MIGRAINES AND SOME PERTINENT BASELINE CHARACTERISTICS (i.e. NUMBER OF HEADACHES TREATED, USE OF prophylactic medications) not described. Did not report % of patients with relief of Headache Pain.

CONCLUSION: THIS STUDY DEMONSTRATED EQUIVALENCE OF DICLOFENAC-K AND HIGH DOSE SUMATRIPTAN FOR HEADACHE RELIEF, WITH A SLIGHTLY FASTER ONSET FOR DICLOFENAC. NAUSEA AND VOMITING WERE REDUCED IN THE DICLOFENAC GROUPS COMPARED TO THE SUMATRIPTAN GROUP.

# 20 /23 **FIG. 27**

# TALKING POINTS WITH PATIENTS



1. IT IS IMPORTANT TO GUIDE EXPECTATIONS AT THE OUTSET, TO ALLOW 6 MONTHS FOR MEDICATIONS TO WORK. THIS FIGURE IS OF 164 PTS TREATED WITH TRETINOIN OR TRETINOIN AND ORAL MINOCYCLINE. IN TIME, MOST PATIENTS ACHIEVE SUCCESSFUL OUTCOMES. BUT THOSE PATIENTS WHO CANNOT ACCEPT THE NEED TO WAIT 3 TO 5 MONTHS FOR RESULTS WILL USUALLY BE DISAPPOINTED. ADAPTED FROM CUNLIFFE, WJ. J EUR ACAD DERMATOL. 1992; 1:43–52 AND KATSAMBAS et al. ACTA DERM VENEREOL. 1989 S143:35–9.

# PRINTABLE FLOW SHEET FOR CHART:

# PRINT ACNE LESION FLOW SHEET (1 PAGE) PROVIDES A QUANTITATIVE OBJECTIVE SCORING SYSTEM FOR ASSESSING ACNE. 172 OTHER INTERNET LINKS OF VALUE: http://www.rocheusa.com/products/accutane/pi.html: A LINK TO THE ROCHE WEBSITE ABOUT ACCUTANE. IT CONTAINS THE PATIENT CONSENT FORM FOR STARTING ISOTRETINOIN, ALONG WITH INFORMATION FOR THE PATIENT ABOUT SIDE EFFECTS. 174 http://www.fda.gov/cder/drug/infopage/accutane/default.htm: A LINK TO THE FDA'S ACCUTANE INFORMATION WEBSITE PRINT NOW PRINT LATER

PATIENT CONSENT FORM:

to be completed by the patient, her parent /guardian\* AND SIGNED BY HER PRESCRIBER.

PLEASE READ EACH ITEM BELOW AND INITIAL IN THE SPACE PROVIDED TO INDICATE THAT YOU UNDERSTAND EACH ITEM AND AGREE TO FOLLOW YOUR PRESCRIBER'S INSTRUCTIONS DO NOT SIGN THIS CONSENT AND DO NOT

IAKE ACCUTANE IF THERE IS ANYTHING THAT YOU DO NOT UNDERSTAND. A PARENT OR GUARDÍAÑ OF A MINOR PATIENT MUST

ALSO READ AND UNDERSTAND EACH ITEM BEFORE SIGNING THE CONSENT.

IS USED TO TREAT SEVERE NODULAR ACNE THAT DID NOT GET BETTER WITH OTHER TREATMENTS INCLUDING ORAL ANTIBIOTICS. (PATIENT'S NAME) UNDERSTAND THAT ACCUTANE IS A VERY POWERFUL MEDICINE WITH THE POTENTIAL FOR SERIOUS ADVERSE EFFECTS THAT

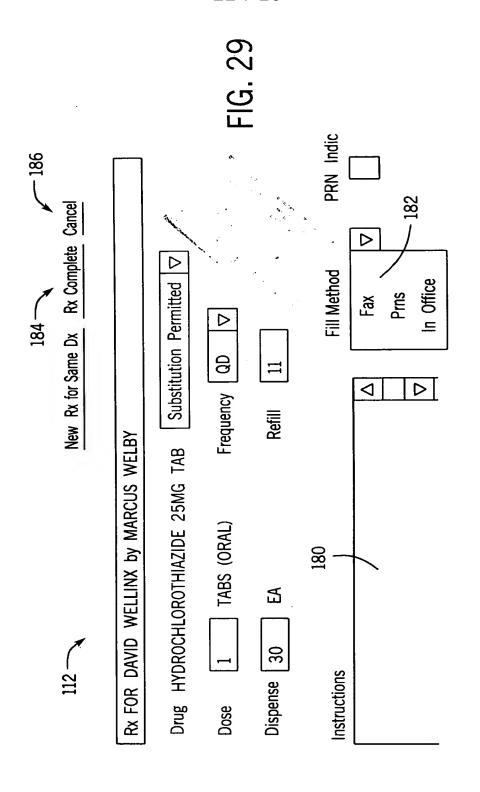
INITIALS

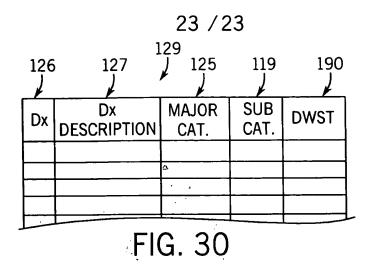
2. I UNDERSTAND THAT I MUST NOT TAKE ACCUTANE (ISOTRETINOIN) IF I AM PREGNANT. I UNDERSTAND THAT I MUST NO TAKE ACCUTANE IF I AM ABLE TO BECOME PREGNANT AND AM NOT USING THE REQUIRED TWO SEPARATE FORMS OF EFFECTIVE METHODS OF BIRTH CONTROL

INITIALS: -

3. I UNDERSTAND FROM MY PRESCRIBER THAT ALTHOUGH NOT EVERY FETUS EXPOSED TO ACCUTANE HAS RESULTED IN DEFORMED CHILD, THERE IS AN EXTREMELY HIGH RISK THAT MY UNBORN BABY COULD HAVE SEVERE BIRTH DEFECTS IF AM PREGNANT OR BECOME PREGNANT WHILE TAKING ACCUTANE IN ANY AMOUNT EVEN FOR SHORT PERIODS OF TIME. POTENTIALLY ANY FETUS EXPOSED DURING PREGNANCY CAN BE AFFECTED

INITIALS:





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190	164	160	170	142
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Pt Dx PRESCRIPTION STOP REASON

FIG. 32